AF/3731

PTO/SB/21 (09-04)
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JFW

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission

| | |
|---|---|
| Application Number | 09/922,996 |
| Filing Date | August 1, 2001 |
| First Named Inventor | DOUK, Nareak |
| Art Unit | 3731 |
| Examiner Name | NGUYEN, V.X. |
| Attorney Docket Number | PA563 CIP2 |

## ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
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- [✓] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):
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Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Medtronic Vascular, Inc. | | |
| Signature | James F. Crittenden | | |
| Printed name | James F. Crittenden | | |
| Date | October 27, 2005 | Reg. No. | 39,560 |

## CERTIFICATE OF TRANSMISSION/MAILING

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| Signature | Claire R. Lynch | | |
| Typed or printed name | Claire R. Lynch | Date | October 27, 2005 |

PTO/SB/17 (12-04)
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriate Act. 2005 (H.R. 4818)

# FEE TRANSMITTAL
## For FY 2005

___ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 500.00

| Complete if Known | |
|---|---|
| Application Number | 09/922,996 |
| Filing Date | August 1, 2001 |
| First Named Inventor | DOUK, Nareak |
| Art Unit | 3731 |
| Examiner Name | NGUYEN, V.X. |
| Attorney Docket Number | PA563 CIP2 |

**METHOD OF PAYMENT** (check all that apply)

___ Check ___ Credit Card ___ Money Order ___ None ___ Other (please identify): _____

X Deposit Account Deposit Account Number: 01-2525 Deposit Account Name: Medtronic Vascular, Inc.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

X Charge fee(s) indicated below

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X Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17

X Credit any overpayments

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## FEE CALCULATION

### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

| Application Type | FILING FEES Fee ($) | FILING FEES Small Entity Fee ($) | SEARCH FEES Fee ($) | SEARCH FEES Small Entity Fee ($) | EXAM. FEES Fee ($) | EXAM. FEES Small Entity Fee ($) | Fees Paid (4) |
|---|---|---|---|---|---|---|---|
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

### 2. EXCESS CLAIM FEES

| Fee Description | Fee ($) | Small Entity Fee ($) |
|---|---|---|
| Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent | 50 | 25 |
| Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent | 200 | 100 |
| Multiple dependent claims | 360 | 180 |

Total Claims _____ - 20 or HP = _____ x _____ = _____ Extra Claims / Fee ($) / Fee Paid ($)

HP = highest number of total claims paid for, if greater than 20

Indep. Claims _____ - 3 or HP = _____ x _____ = _____ Extra Claims / Fee ($) / Fee Paid ($)

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims Fee ($) _____ Fee Paid ($) _____

### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = _____ / 50 = _____ (round **up** to a whole number) x _____ = _____ Extra Sheets / Number of each additional 50 or fraction thereof / Fee ($) / Fee Paid ($)

### 4. OTHER FEE(S)

| | Fee Paid ($) |
|---|---|
| Filing a Brief in Support of an Appeal | $500.00 |

**SUBMITTED BY**

| | | | | | |
|---|---|---|---|---|---|
| Signature | James F. Crittenden | Registration No. (Attorney/Agent) | 39,560 | Telephone | 978/739-3075. |
| Name (Print/Type) | James F. Crittenden | | | Date | October 27, 2005 |

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I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in the envelope addressed to: Mail Stop APPEAL BRIEF - PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 27, 2005.

By: _____
Kimberly Melvin

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | | |
|---|---|---|---|---|
| Appln. No. | : | 09/922,996 | Confirmation No.: | 9126 |
| Applicant | : | DOUK, Nareak | | |
| Filed | : | August 1, 2001 | | |
| TC/A.U. | : | 3731 | | |
| Examiner | : | NGUYEN, V. X. | | |
| Docket No. | : | PA563 CIP2 | | |
| Customer No. | : | 28390 | | |
| Title | : | Temporary Device for Capturing Embolic Material | | |

**ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**APPEAL BRIEF**

Mail Stop APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The appellant appeals the rejection of Claims 1-6, 8-13, 19-22, 24-27 and 31-36 in the above-captioned application. These claims were rejected in the Final Office Action dated June 14, 2005.

This Appeal Brief is being filed in accordance with the rules of 37 C.F.R. § 41.37 and includes a Claims Appendix, an Evidence Appendix, and a Related Proceedings Appendix.

## I. REAL PARTY IN INTEREST

The real party in interest is Medtronic Vascular, Inc. Medtronic Vascular, Inc. previously was known as Medtronic AVE, Inc. Medtronic Vascular, Inc. is the assignee of record.

## II. RELATED APPEALS AND INTERFERENCES

The appellant knows of no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this Appeal.

## III. STATUS OF CLAIMS

On September 12, 2005, appellant appealed from the final rejections of Claims 1-6, 8-13, 19-22, 24-27 and 31-36, as listed in the Claims Appendix. Claims 7, 14-18, 23, 28-30 and 37-38 were previously withdrawn from consideration pursuant to a restriction requirement.

**Prosecution History of Claims Prior to June 14, 2005 Final Office Action**

The above-captioned application was originally filed on August 1, 2001, with Claims 1-38.

On October 20, 2003, when responding to a Restriction Requirement mailed September 30, 2003, appellant provisionally elected Claims 1-36 with traverse.

On March 29, 2004, when responding to an Office Action mailed December 29, 2003, appellant acknowledged a final election/restriction requirement and withdrew Claims 7, 14-18, 23, 28-30 and 37-38. Appellant amended Claim 25.

On August 16, 2004, when responding to a Final Office Action mailed June 15, 2004, appellant filed an amendment to Claim 1, which was not entered.

On October 14, 2004, when responding to the Final Office Action mailed June 15, 2004 and an Advisory Action mailed September 21, 2004, appellant re-filed the above amendment to Claim 1.

On March 24, 2005, when responding to an Office Action mailed December 28, 2004, appellant did not amend, cancel or add any claims.

On August 9, 2005, when responding to a Final Office Action mailed June 14, 2004, appellant did not amend, cancel or add any claims.

## IV. STATUS OF AMENDMENTS

As disclosed in Section III above, appellant filed a Reply on August 9, 2005 that did not amend, cancel or add any claims. This "amendment" was not entered.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

This application is directed to filters for capturing emboli in a blood vessel during an interventional vascular procedure and then removing the captured emboli from the patient after completion of the procedure. The claims being appealed are directed particularly to a capture element mounted on a guidewire that can also be used to direct an interventional catheter to a treatment site within a patient.

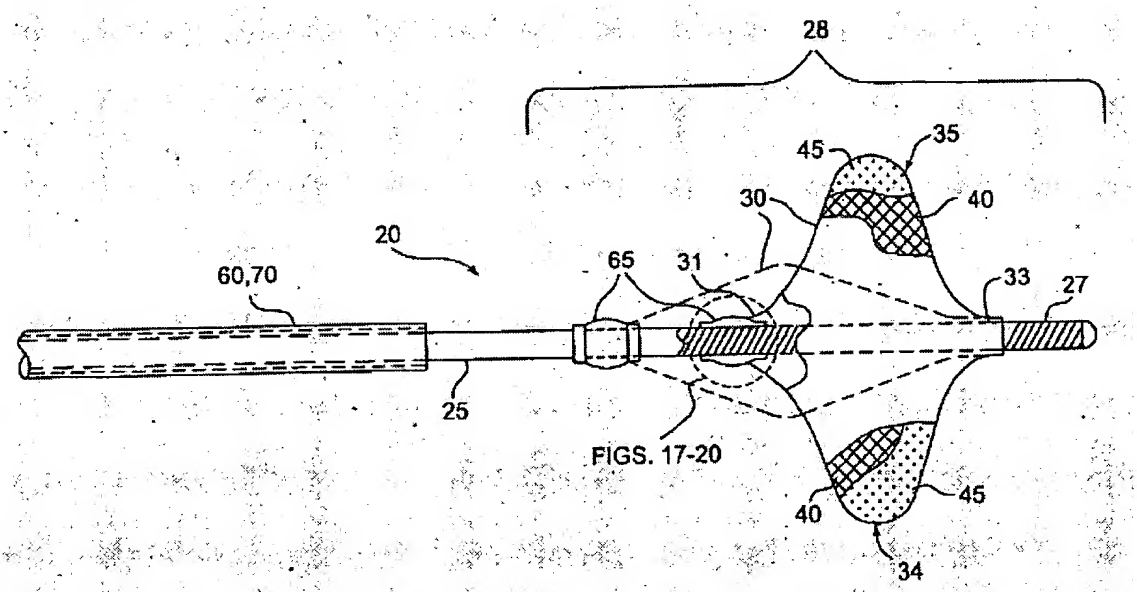
### Independent Claim 1

As recited in the Claim Appendix, Claim 1 reads as follows:

> Claim 1: A temporary device for capturing embolic material from a bodily fluid within a vessel of a patient, the device comprising:
>
> an elongate guidewire having a distal region;
>
> a capture element disposed about the guidewire distal region, the capture element having distal and proximal ends and a central region, wherein relative longitudinal movement between the distal and proximal ends accompanies a transformation of the capture element between a generally tubular closed configuration and a deployed configuration wherein the central region is expanded into apposition with the vessel; and
>
> at least one latch fixed to the guidewire distal region and being releasably engageable with the proximal end of the capture element to temporarily retain the capture element in the deployed configuration.

With reference to Figure 3 below, which illustrates an embodiment related to Claim 1, device 20 includes guidewire 25 having distal region 28. See ¶ 0027, lines 1-2. Capture element 30 is disposed about guidewire distal region 28 and has proximal and distal ends 31, 33, respectively and central region 34. Longitudinal movement between capture element proximal and distal ends 31, 33 accompanies a transformation of capture element 30 between a generally tubular closed configuration shown in Figure 5 below, and a deployed configuration wherein central region 30 is expanded. See ¶ 0028, lines 1-9. Latch 65 is fixed to guidewire distal region 28. See ¶ 0035, lines 11-15. Latch 65 is releasably engageable with capture element proximal end 31 to temporarily retain capture element 30 in the deployed configuration. See ¶ 0030, lines 6-8. Figure 3 illustrates an

embodiment having two latches 65 such that capture element 30 is deployable to two different expanded sizes. See ¶ 0038, lines 1-6.




FIGS. 17-20

FIG. 3

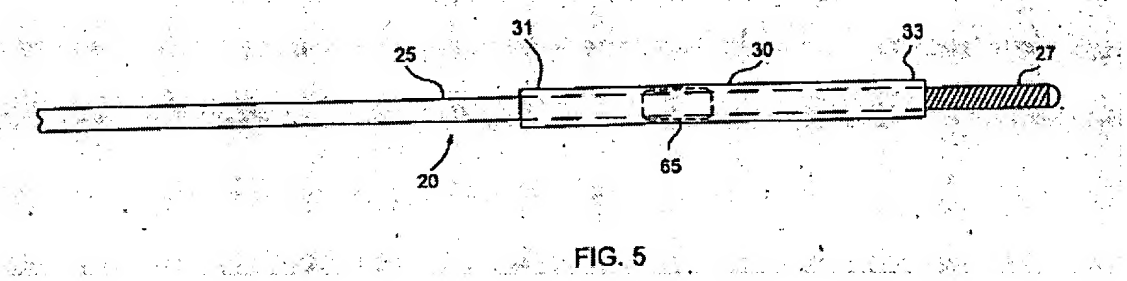



FIG. 5

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-6, 8-13, 19-22, 24-27 and 31-36 stand rejected as being anticipated by U.S. Patent No. 6,001,118 to Daniel *et al* ("Daniel").

## VII. ARGUMENT

Claims 1-6, 8-13, 19-22, 24-27 and 31-36 are not properly rejected under 35 U.S.C. § 102(b) because Daniel does not disclose every limitation of the claims.

**Claims 1-6, 8-13, 19-22, 24-27 and 31-36 Are Allowable Over Daniel Because Daniel Does Not Disclose A Latch Fixed To A Guidewire Distal Region And Being Releasably Engageable With A Proximal End Of A Capture Element**

In the Office Action, the Examiner rejects Claims 1-6, 8-13, 19-22, 24-27 and 31-36 under 35 U.S.C. § 102(b) based on U.S. Patent No. 6,001,118 to Daniel *et al.*, issued December 14, 1999. The Examiner asserts the following three arguments *inter alia.*

A. Item 292 is Considered as Teaching Appellants' Claimed Latch Element

> Item 292 is considered a latch defined as a device to get hold of or obtain another item that is used to get a hold of the guide-wire; and where the latch of Daniel is capable of being releasably engageable with the capture element to retain the capture element in the deployed configuration. See Final Office Action, page 2.

B. Dictionary Definition of Appellants' Term "Latch"

The Examiner relies on a Merriam-Webster dictionary definition of "latch" quoted as "any various devices in which mating mechanical parts engage to fasten something." See Final Office Action, page 3.

C. Relative Movement of Collars 288 and 292 Teaches Releasable Engagement

> Daniel discloses that spring 294 causes collars 288 and 292 to move toward one another, relatively (see col. 12, lines 29-32). Therefore, element 292 as disclosed in Daniel is "capable of being releasable engageable with the capture element 290", as broadly recited in the claims. See Advisory Action Continuation Sheet.

Appellants aver that the Examiner has improperly interpreted the "latch" requirements of the claims and has disregarded the specific claim limitation that the latch is engageable with the proximal end of the capture element. Appellants respectfully disagree with the Examiner's characterizations of the teachings of Daniel with regard to the latch element of Claim 1. Appellants also assert that a relevant portion of the dictionary definition quoted by the Examiner was omitted.

**Daniel**

Daniel is directed to a system for capturing emboli in a body lumen. An expandable emboli capturing member is mounted proximate a distal end of an elongate member, and is movable between a radially expanded position and a radially contracted position. See column 2, lines 26-31. Daniel discloses device 280 including outer tube or hypotube 282, which is coupled to a source (not shown) that selectively provides fluid pressure through inflation lumen 296. See FIG. 19 (below) and column 11, line 49 – column 12, line 49.

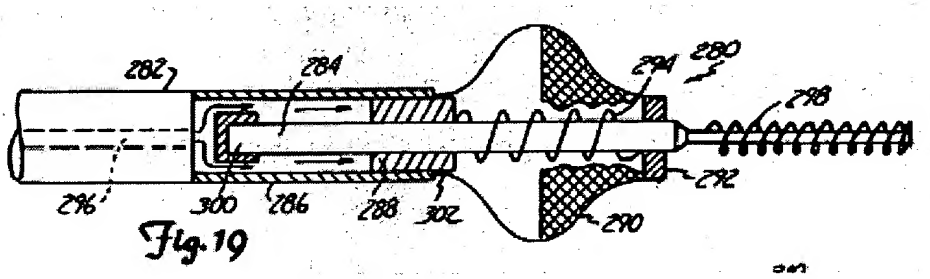


Fig. 19

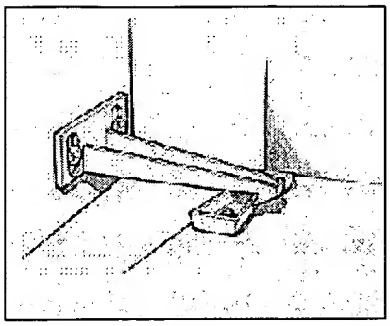
Transition tube 286 extends from outer tube 282. Inner wire or core wire 284 is coupled at its proximal end 300 to transition tube 286 and extends distally there from. Expandable member 290 is attached to core wire 284 by collars 288 and 292. Fixed collar 292 is fixedly attached between the distal end of expandable member 290 and core wire 284. Sliding collar or "movable collar" or "movable plunger" 288 is affixed to and controls the axial position of proximal end 302 of expandable member 290. Under hydraulic pressure, sliding collar 288 is moved, like a piston, along the annular space

between core wire 284 and transition tube 286. As collar 288 moves closer to collar 292, expandable member 290 is forced to buckle and expand outwardly. Optional spring 294 is biased to force collars 288 and 292 away from each other.

Claim 1 requires, in part, a "latch fixed to the guidewire distal region and being releasably engageable with the proximal end of the capture element." Appellants assert that the application uses the ordinary and accepted meaning of the term "latch," although specific latches 65, 165, 265, 365 and 465 are believed to be novel and inventive elements of the combinations that are disclosed and claimed. See figures 17-20. One example having ordinary meanings of the term "latch" is the dictionary definition cited in the Examiner's argument B above, which reads in full:

> **latch** (noun): any of various devices in which mating mechanical parts engage to fasten but usually not to lock something: **a**: a fastener (as for a door) consisting essentially of a pivoted bar that falls into a notch **b**: a fastener (as for a door) in which a spring slides a bolt into a hole; (emphasis supplied, *Merriam Webster Online*)

The emphasized phrase above, omitted by the Examiner, refers to the reversibility that all types of latches have in common; that is, all latches have two conditions, e.g. being engaged or disengaged, being open or closed, being latched or released. Releasability is inherent in the above dictionary definition: The bar may be lifted out of the notch or the bolt may be slid out of the hole (as to allow the door to be opened). Among numerous types of latches in many different fields, the following illustrations are merely two examples of latches, including a "childproof" cabinet latch and an aircraft engine cowl latch assembly.



"Childproof" Cabinet Latch

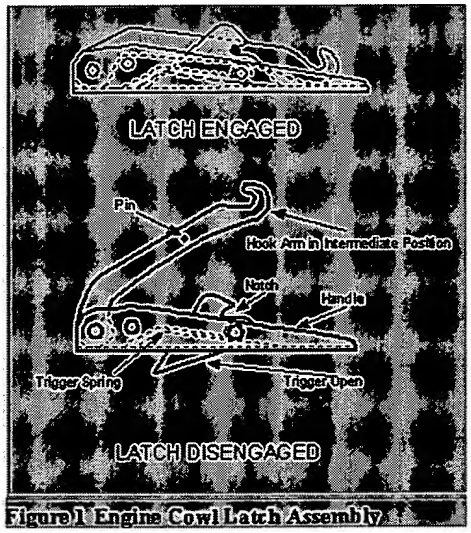



Figure 1 Engine Cowl Latch Assembly



In view of the above examples of common usage of the term "latch," all latches can be considered to be "releasably engageable" with a mating mechanical part. Claim 1 requires that the latch be "releasably engageable with the proximal end of the capture element." The Examiner has improperly interpreted the "latch" requirements of the claims in argument A above, and has incorrectly cited a non-releasable, or permanent attachment between two elements in Daniel; argument A states: "Item 292 is considered a latch defined as a device to get hold of or obtain another item that is used to get a hold of the guide-wire."

Nowhere does Daniel teach element 292 as being capable of releasably engaging the capture element, as asserted in Examiner's arguments A and C above. On the contrary, element 292 is described explicitly as a "fixed collar." Fixed collar 292 is also an inherently fixed connection between the distal end of expandable member 290 and core wire 284. See column 11, line 49 – column 12, line 49. On page 2 of the Office Action mailed December 28, 2004, the Examiner states, in regard to Claims 2-5, that Daniel's "capture element (290) is fixed to the guide-wire." Appellants concur with this characterization and further point out that the only fixed connection between expandable member 290 and core wire 284 disclosed in Daniel is through fixed collar 292.

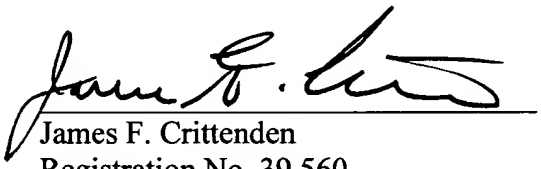
In summary, Daniel does not disclose a "latch fixed to the guidewire distal region and being releasably engageable with the proximal end of the capture element," as required in Claim 1. In particular, Daniel's element 292 is not a latch, according to the ordinary and accepted meaning of the term. Element 292 is also not releasably engageable with any other element. Finally, element 292 is specifically not releasably engageable with the proximal end of a capture element. Therefore, Daniel fails to anticipate the claims because the reference fails to teach each and every element recited in the claims. Claims 2-6, 8-13, 19-22, 24-27, 31-36 depend directly or indirectly from Claim 1 and are patentable for at least the reasons discussed above regarding Claim 1.

**Conclusion**

In view of the above arguments distinguishing Claims 1-6, 8-13, 19-22, 24-27 and 31-36 over the art of record, Appellants respectfully request that the rejection of these claims be reversed.

Date: October 27, 2005

Respectfully submitted,



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## CLAIMS APPENDIX

Claim 1: A temporary device for capturing embolic material from a bodily fluid within a vessel of a patient, the device comprising:

an elongate guidewire having a distal region;

a capture element disposed about the guidewire distal region, the capture element having distal and proximal ends and a central region, wherein relative longitudinal movement between the distal and proximal ends accompanies a transformation of the capture element between a generally tubular closed configuration and a deployed configuration wherein the central region is expanded into apposition with the vessel; and

at least one latch fixed to the guidewire distal region and being releasably engageable with the proximal end of the capture element to temporarily retain the capture element in the deployed configuration.

Claim 2: The device of claim 1 wherein the distal end of the capture element is longitudinally fixed to the guidewire.

Claim 3: The device of claim 1 wherein the capture element is removably slidable along the guidewire, the capture element having been selectively placed about the guidewire and pushed onto the guidewire distal region, the device further comprising a stop element disposed on the guidewire distal region, the stop element being capable of blocking advancement distal thereto by the distal end of the capture element.

Claim 4: The device of claim 1 wherein the at least one latch is positioned between the distal and proximal ends of the capture element when the capture element is in the closed configuration.

Claim 5: The device of claim 1 further comprising a first anti-inversion stop fixed to the guidewire at a location distal of the at least one latch, the first anti-inversion stop being capable of preventing advancement distal thereto by the proximal end of the capture element.

Claim 6: The device of claim 1 further comprising an elongate, hollow, deployment rod slidably and removably disposed about the guidewire, the deployment rod being operable to push the proximal end of the capture element distally along the guidewire and over the at least one latch, thereby effectuating the transformation of the capture element from the closed configuration to the deployed configuration.

Claim 8: The device of claim 6 wherein the deployment rod comprises an elongate, wire-like, proximal shaft and a relatively short tubular distal section.

Claim 9: The device of claim 6 wherein the deployment rod comprises an interventional catheter.

Claim 10: The device of claim 1 wherein the capture element comprises a filter operable, when in the deployed configuration, to allow the bodily fluid to pass there through while simultaneously capturing the embolic material therefrom.

Claim 11: The device of claim 10 wherein the capture element comprises a tubular braid of filaments.

Claim 12: The device of claim 11 wherein the filaments comprise shape-memory metal wire.

Claim 13: The device of claim 12 wherein the shape-memory metal is nitinol.

Claim 19: The device of claim 1 wherein the capture element comprises a support structure capable of the transformation between the closed and deployed configurations, the support structure being covered with an elastic membrane.

Claim 20: The device of claim 19 wherein the support structure comprises a tubular braid of filaments.

Claim 21: The device of claim 19 wherein the support structure comprises a first tube having been slotted or slit to form generally longitudinal struts.

Claim 22: The device of claim 21 wherein the first tube comprises nitinol.

Claim 24: The device of claim 19 wherein the elastic membrane is porous, such that the capture element comprises a filter operable, when in the deployed configuration, to allow the bodily fluid to pass therethrough while simultaneously capturing the embolic material therefrom.

Claim 25: The device of claim 19 wherein the elastic membrane comprises natural rubber, synthetic rubber, thermoplastic elastomer or thermoset polymer.

Claim 26: The device of claim 1 wherein the at least one latch has distal and proximal ends, and a normal shape and size suitable for engagement with the proximal end of the capture element, the at least one latch being reversibly operable to allow the proximal end of the capture element to slide there over.

Claim 27: The device of claim 26 wherein the proximal end of the at least one latch is fixed to the guidewire.

Claim 31: The device of claim 26 wherein the at least one latch comprises a tubular braid of filaments.

Claim 32: The device of claim 26 wherein the normal shape of the at least one latch comprises one or more latch engagement surfaces for engagement with the proximal end of the capture element.

Claim 33: The device of claim 32 wherein the one or more latch engagement surfaces are circumferentially arranged in a middle region of the at least one latch.

Claim 34: The device of claim 26 further comprising an elongate, hollow, closing rod slidably and removably disposed about the guidewire, the closing rod being operable to advance over at least a portion of the at least one latch to selectively compress the normal shape and size thereof, thereby disengaging the latch from the proximal end of the capture element.

Claim 35: The device of claim 34 wherein the closing rod comprises an elongate, wire-like, proximal shaft and a relatively short tubular distal section.

Claim 36: The device of claim 34 wherein the closing rod comprises an interventional catheter.

## EVIDENCE APPENDIX

[NONE]

## RELATED PROCEEDINGS APPENDIX

[NONE]